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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,828

04/09/2004

Hector F. DeLuca

1256-00949

1399

26753

7590

09/25/2008

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

09/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,828	Applicant(s) DELUCA ET AL.	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 22-71 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 22-71 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2008 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

3. The rejection of claims 1-17 and 22-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 5,843,928; 6,392,071; 6,440,953; 6,482,812; 6,537,981; 6,696,431; 6,774,251; 6,806,262; 6,894,037; 6,992,074; 7,053,075; 7,115,594; 7,208,484; 7,214,670; 7,214,671; 7,232,810; 7,241,747; 7,241,909 and 7,244,719 in view of Bishop et al. (US 5,972,917) or Deluca et al. (WO 96/16035) is maintained and claims 1-17 and 22-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos.

Art Unit: 1612

**6,114,317; 6,566,352; 6,579,861; 6,627,622; 6,887,860; 7,094,774; 7,141,558;
7,241,748 and 7,300,925 in view of Bishop et al. (US 5,972,917) or DeLuca et al.
(WO 96/16035).**

Applicant argues the biological activities of vitamin D compounds are unpredictable and, thus, one skilled in the art will not be able to predict with any certainty the activity of any particular vitamin D compound until such vitamin D is actually tested for such activities. Applicant's argument was considered but not persuasive for the following reasons.

First, in order to argue unexpected and/or unobvious results, comparison between the closest prior art compound and the claimed compound is necessary. It is important that said is true side-by-side comparison, i.e., experimentation done under identical conditions. Here, applicant is arguing unexpected/unobvious results based on data from a number of references.

According to applicant, the presently claimed compound "has little, if any calcemic activity" and, thus, would not be useful in treating metabolic bone diseases. However, like the claimed 18,19-dinor-2-methylene analogs, the art teaches the corresponding 19-nor-2-methylene analogs have "little, if any calcemic activity" (see for example, US 6,440,953, col. 2, lines 48-49; US 6,579,861, col. 2, lines 53-54). As taught by the art, the introduction of 2-methylene group changes the character of the hydroxyl groups which are crucial for the biological activity of vitamin D compounds (see for example, US 6,579,861, col. 2, lines 1-20). Thus, the skilled artisan in the art, based on the teachings of the prior art, would have the reasonable expectation that the

Art Unit: 1612

corresponding 18,19-dinor-analog of the prior art 19-nor-2-methylene vitamin D compounds would also have little calcemic activity.

Vitamin D compounds have a variety of activities and are known to be useful in a number of diseases, including osteoporosis. The art also teaches changes in the calcemic activity of vitamin D compounds based on the absence/presence of hydrogen and/or methyl(methylene) at the 18- and/or 19-positions, as evidenced by applicant's discussion in the response dated August 11, 2008. However, as discussed above, the art also teaches the introduction of 2-methylene groups affects the biological activity of vitamin compounds, i.e., results in compounds with little, if any, calcemic activity. Based on said knowledge and the teaching of 19-nor-2-methylene vitamin D compounds, the claimed 18,19-dinor-2-methylene vitamin D compounds are prima facie obvious.

For these reasons and those given in the previous Office Actions, the rejection of claims 1-17 and 22-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 5,843,928; 6,392,071; 6,440,953; 6,482,812; 6,537,981; 6,696,431; 6,774,251; 6,806,262; 6,894,037; 6,992,074; 7,053,075; 7,115,594; 7,208,484; 7,214,670; 7,214,671; 7,232,810; 7,241,747; 7,241,909 and 7,244,719 in view of Bishop et al. (US 5,972,917) or Deluca et al. (WO 96/16035) is maintained and claims 1-17 and 22-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,114,317; 6,566,352; 6,579,861; 6,627,622; 6,887,860;

Art Unit: 1612

7,094,774; 7,141,558; 7,241,748 and 7,300,925 in view of Bishop et al. (US 5,972,917) or DeLuca et al. (WO 96/16035).

4. The provisional rejection of claims 1-17 and 22-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/997,698 and 11/351,874 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035) is maintained and claims 1-17 and 22-71 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 11/697,414; 11/697,434 and 11/697,436 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035).

Applicant's argument and the examiner's response are as discussed above in #3.

For these reasons and those given in previous Office Actions, the provisional rejection of claims 1-17 and 22-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/997,698 and 11/351,874 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035) is maintained and claims 1-17 and 22-71 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 11/697,414; 11/697,434 and 11/697,436 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035).

Telephone Inquiry

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio, Ph.D./
Primary Examiner, Art Unit 1612